Fixos
Forefoot & Mid-foot Screw System

Operative Technique

- Cannulated Compression Screws
  2.5mm SV, 3.0mm HV, 3.5mm CS, 4.0mm MV
- Twist-Off Screws
  2.0mm WS, 2.7mm KS
This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery. All non-sterile devices must be cleaned and sterilized before use. Follow the appropriate instruction for use (IFU). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

See package insert for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Warning:
Fixation Screws:
Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
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**Indications**

The Fixos Screws are indicated for fixing and stabilizing the elective osteotomies of the mid-foot bones, the metatarsal and phalanges of the foot only.

**Contraindications**

The following contraindications may be of a relative or absolute nature and must be taken into account by the attending surgeons:

- Acute or chronic infections, local or systemic.
- Surgical procedures other than those mentioned in the Indications section.

The combination of this implant with implants of another origin is contraindicated.

Do not use on patients allergic to the components of the product or having known allergies.

Do not use twist–off screws in osteoporotic bones.

**Precautions**

Stryker Osteosynthesis systems have not been evaluated for safety and use in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling or respective operative technique. Detailed information is included in the instructions for use being attached to every implant.

Possible side effects during the implantation of osteosynthesis devices are, delay in consolidation, pseudarthrosis, the implant pulling free, rupture or deformation of all or part of the implant, infection, hematoma, venous thrombosis, pulmonary embolism and cardiovascular problems.

Factors capable of compromising implantation success are bone pathology, osteoporosis, bone tumors, systemic or metabolic problems and infectious diseases, senility, mental illness, abuse of illegal drugs, prescription drugs or alcohol, excess weight, intense professional or sporting physical activity that exposes the implant to excessive or repeated loads, risk of conflict with other implants, risk of articular conflict.

See package insert for warnings, precautions, adverse effects and other essential product information.
The Fixos screw range includes 6 different size options to address a large variety of fusions and osteotomies. Each screw and its associated instrumentation has been especially designed to answer surgeon needs such as:

- Compression
- Precise Placement – Specific guide wire diameters
- Headless and low-profile head design to reduce soft tissues injuries

All Fixos screws are made of Titanium alloy Ti 6Al-4V.
Overview & Implant Features

Cannulated Compression Screw

- Headless screw
- Different thread pitch between the head and the distal shaft to allow for compression
- Self-tapping
- Self-drilling (for 2.5mm SV, 3.5mm CS & 4.0mm MV)
- One step drilling & countersinking drill bit (for 2.5mm SV, 3.0mm HV & 3.5mm CS)
- Hexagonal driving recess

Example of Applications

<table>
<thead>
<tr>
<th>Scarf Osteotomy</th>
<th>Phallangeal Osteotomy</th>
<th>Chevron &amp; Austin Osteotomy</th>
<th>Forefoot &amp; Mid-foot Fusion &amp; Osteotomy</th>
</tr>
</thead>
</table>

2.5mm SV

- Head thread Ø3.4mm
- Shank Diameter Thread Base 1.7mm
- Distal Thread Ø2.5mm, Cortical anchorage
- Kirshner-Wire Ø0.9mm
- From 10 – 30mm each 2mm

3.0mm HV*

- Head thread Ø4.0mm
- Shank Diameter Thread Base 2.0mm
- Distal Thread Ø3.5mm, Cortical anchorage
- Kirshner-Wire Ø1.1mm
- From 10 – 30mm each 2mm

3.5mm CS

- Head thread Ø4.2mm
- Shank Diameter Thread Base 2mm
- Distal Thread Ø3.5mm, Cancellous anchorage
- Kirshner-Wire Ø1.1mm
- From 14 – 36mm each 2mm

4.0mm MV

- Head thread Ø5mm
- Shank Diameter Thread Base 2.7mm
- Distal Thread Ø4mm, Cortical anchorage
- Kirshner-Wire Ø1.4mm
- From 18 – 60 each 2mm

* Custom Order
Overview & Implant Features

Twist-Off Screw

- Cancellous anchorage
- Self-tapping
- Self-drilling
- Power insertion and final insertion with a specific screwdriver
- Low profile head

Example of Applications

2.0mm WS

Metatarsal Weil Osteotomy of lesser rays

2.7mm KS

Chevron/Austin Osteotomy

General warning:
- Excessive rotation speed during screwing and drilling could lead to excessive heat generation
- Excessive torque applied during screwing can lead to screw head or screw driver damage and can make screw extraction difficult. This could lead to extended bone damage which could require additional specific measures (additional surgery, change of surgery method, revision surgery)
- Pay attention to avoid any unexpected soft tissue irritation especially during cutting, drilling, milling and screw / K-Wire insertion

From 11 – 16mm each 1mm

From 14 – 22 each 2mm
# Instrumentation Features

## Color coded

Screws are color-coded by diameter to easily identify associated instrumentation.

<table>
<thead>
<tr>
<th>Screws (mm)</th>
<th>Screwdriver</th>
<th>Drill Bits/Guide/Countersink**</th>
<th>K-Wires</th>
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<tr>
<td>2.5 SV</td>
<td>XTV004001</td>
<td>XFO051201</td>
<td>AGK09070M &amp; AGK0209070M (Ø0.9mm)</td>
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<td>XTV006001</td>
<td>XFO073200</td>
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<td>3.0 HV*</td>
<td>XTV001001</td>
<td>XFO041201/XFO021201</td>
<td>AGK10070 &amp; AGK0210070 (Ø1.0mm)</td>
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<td>3.5 CS</td>
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<td>AGK10070 &amp; AGK0210070 (Ø1mm)</td>
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<td>4.0 MV</td>
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<td>XV1MQ1427</td>
<td>AGK0214100 &amp; AGK0214150 (Ø1.4mm)</td>
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<td>2.0 WS</td>
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<tr>
<td>2.7 KS</td>
<td>XTV005001</td>
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</table>

The screwdriver can be used to finalize the insertion.

* Custom order
** Depending on Complete Tray options
Instrumentation Features

Drill Bits
2.5mm SV, 3.0mm HV and 3.5mm CS cannulated compression screws are provided with several drill bit lengths to perform cortical or bi-cortical drilling and countersinking according to the patient anatomy and the surgical technique.

For intermediary screw lengths, it could be necessary to employ two different drill bit lengths to perform the countersink.

Countersink Option 3.8mm

Cannulated or solid drill bit*
- 12 or 31mm for 2.5 SV screws
- 12, 17, 23, 31mm for 3.0 HV and 3.5 CS screws

Gauge and Ruler

Gauge
In case of bi-cortical anchorage without K-Wire positioning, the non cannulated gauge (XJA002004) may be used to identify the appropriate screw size. Ensure that the tip of the gauge hangs upon the second cortex for accurate screw length measurement.

Ruler
Measure screw length by using the cannulated ruler (REF XJA030170 for 2.5 SV, 3.0 HV and 3.5 CS screws or REF XJA003001 for 4.0 MV screws). Slide it over the K-Wire and position it in direct contact with the bone.

The rulers have two scales. Make sure to use the appropriate scale according to the K-Wire length (70, 100 or 150mm).

For accurate screw measurement:
- Subtract appropriately for any anticipated segment fixation or intersegmentary fixation due to compression of the screw during insertion
- Ensure that the measuring ruler is placed perpendicularly to the bone surface for better accuracy. Otherwise subtract appropriately to ensure a well seated head without overpassing the second cortex

Screwdriver Assembly

Pull the handle collar of the driver and insert the driver tips (XTV006003). The flat surface of the driver tips needs to align with the arrow on the screwdriver handle as pictured.
Cannulated Compression Screws – 2.5mm SV

The 2.5mm SV screw are cannulated compression screws with a self-drilling tip.

Reduction & K-Wire Insertion
After performing the osteotomy, a K-Wire (REF AGK09070M / AGK0209070M) may be placed through the osteotomy site for an accurate screw positioning.

Screw Length Identification
Measure screw length by using the cannulated ruler (REF XJA030170) over the K-Wire until the cortical is reached. The scale indicates the depth from the surface of the bone to the tip of the K-Wire.

Note:
The ruler has two scales, use the 70mm scale according to the K-Wire length

The K-Wire should not overpass the second cortex to obtain valuable measurement.

Screw Insertion
In some circumstances such as hard bone density, pre-drilling and countersinking may be desired (example: Scarf osteotomy). After assessing the bone nature proceed following one of these 2 options.

Option 1: Self-drilling
Insert the screw over the K-Wire with a power tool linked to the AO quick coupling screwdriver bit (REF XTV006001) until the second cortex has been reached.
Operative Technique

Option 2 & 3: Pre-drilling & Countersinking

Place the long or short cannulated drill bit (REF XFO073200/XFO051201) over the K-Wire according to the patient anatomy and drill until desired depth. The short cannulated drill bit offers a countersinking option to ensure the head of the screw will be completely seated into the bone. Insert the screw with the cannulated screwdriver (REF XTV004001/XTV006001+XME001001) until the second cortex has been reached.

After final insertion, it is recommended to check the final position under fluoroscopy. Remove the K-Wire and proceed to normal surgical closure.

Note: Most of the time it is recommended to perform a pre-drilling before the screw insertion in order to avoid excessive torque transmission.
Cannulated Compression Screws – 3.0mm HV*

3.0mm HV screws have been specifically designed to perform secure and efficient Scarf or Phalangeal osteotomies.

**Reduction**

When reduction is achieved, use the Scarf forceps (REF XPI001001) to stabilize the fragments.

A K-Wire (REF AGK10070 / AGK0210070) may be placed through the osteotomy site for an accurate screw positioning.

**Screw Length Identification**

According to the set composition and the surgical technique, measure the screw length:

- over the K-Wire and before the pre-drilling step, if using the Ruler (XJA030170)
- after the pre-drilling step and the K-Wire removal, if using the gauge (XJA002004)

**Pre-drilling**

Place the appropriate cannulated drill bit with countersink (REF XFO041201, XFO041701, XFO042301, XFO043101) over the K-Wire and drill until the second cortex has been reached. The cannulated drill bit offers a countersinking option to ensure the head of the screw will be completely seated into the bone. 3.0mm HV screws are inserted using bi-cortical anchorage.

* Custom Order
**Operative Technique**

**Screw insertion**

The final seating should be completed by hand using the blue screwdriver (REF XTV001001/XTV006002 + XME001001). After final insertion, confirm the final position under fluoroscopy. Remove the K-Wire and proceed to normal surgical closure.

**Note:**

Pre-drilling can also be performed with solid drill bits* according to the set composition.
Operative Technique

Cannulated Compression Screws – 3.5mm CS

The cannulated compression 3.5mm CS screw was specially designed to achieve a strong cancellous anchorage.

Reduction

When reduction is achieved, use the Chevron Forceps (REF XDA002001) to stabilize the fragments. A K-Wire (REF AGK10070 / AGK0210070) is placed through the osteotomy site for an accurate screw positioning.

Screw Length Identification

Measure screw length by using the cannulated ruler (REF XJA030170) over the K-Wire. The scale indicates the depth from the surface of the bone to the tip of the K-Wire. As cancellous anchorage is desired, remove several mm from your measurements to select the appropriate screw length.

Note:
The ruler has two scales, use 70mm scale according to the K-Wire length.

Drilling & Countersinking

The 3.5 mm CS screws have been designed to be self drilling. In some circumstances such as hard bone density, pre-drilling is recommended.

Place the appropriate cannulated drill guide with countersink (REF XFO041201, XFO041701, XFO042301, XFO043101) over the K-Wire and drill until the desired depth. The cannulated drill guide offers a countersinking step to ensure the head of the screw will be completely seated into the bone (See blue arrow).
**Operative Technique**

**Screw Insertion**

Insert the screw with the power tool linked to AO coupling screwdriver bit (REF XTV006002) or the cannulated Screwdriver (REF XTV001001/ XTV006002 + XME001001).

**Note:**
- If no pre-drilling has been performed, proceed after the countersinking to a power tool insertion.
- Most of the time it is recommended to perform a pre-drilling before the screw insertion in order to avoid excessive torque transmission.

After final insertion, confirm the final position under fluoroscopy. Remove the K-Wire and proceed to normal surgical closure.
Operative Technique

Compression Cannulated Screws - 4.0mm MV

The following example illustrates an MTP arthrodesis.

Joint Stabilization

After joint preparation with Flat Cuts Technique or Cup & Cone Technique, position the double drill guide (REF XVIMQ1427) (K-Wire side) and insert two 1.4mm crossed K-Wires (REF AGK0214150 or AGK0214100) to stabilize the joint.

Screw Length Identification

Measure screw length by using the cannulated ruler (REF XJA003001) over the K-Wire. The scale indicates the depth from the surface of the bone to the tip of the K-Wire.

Note:
The ruler has two scales, use the appropriate scale according to the K-Wire length (100mm or 150mm).

The K-Wire should not overpass the second cortex to obtain valuable measurement.

Drilling & Countersinking

The 4mm MV screws have been designed to be self-drilling. In some circumstances such as hard bone density, pre-drilling is recommended.

Place the appropriate double drill guide, drill-bit side (REF XVIMQ1427) over the K-Wires and drill with the cannulated drill bit (REF XFO094501) until the desired depth.

Countersinking is performed with the cannulated countersink reamer (REF XFR006050) over the K-Wires.
**Operative Technique**

**Screw Placement**

After pre-drilling step, insert the screw manually with the screwdriver bit (REF XTV006003) until the second cortex has been reached.

If no pre-drilling has been performed, proceed, after the countersinking, to a power tool insertion. Most of the time it is recommended to perform a pre-drilling before the screw insertion in order to avoid excessive torque transmission.

Proceed in a similar way to place the second screw, paying attention to not put the two screws in contact.

**Note:**

*Two screws touching each other can lead to screw damage due to excessive screwing torque and could generate unexpected metal fragments.*

After final insertion, the position should be checked under X-Ray. Remove the K-Wire and proceed to normal surgical closure.

**MTP arthrodesis with Plantar screw**
Twist-Off Screws

The Fixos System offers two diameters of twist-off screws. The twist-off screws have been designed to perform faster screw insertion without pre-drilling and countersinking steps.

2.0mm WS screws

The following example describe a Weil osteotomy with a 2.0mm WS screw.

Joint Preparation/Osteotomy

The Weil osteotomy is made with an oscillating saw. The cut (2-3cm length) is made parallel to the sole of the foot. The metatarsal head can be easily positioned and held in place with the expander (REF XEC001001).

Screw Placement

After screw length estimation, insert the twist-off screw, without pre-drilling, with a power tool:

• Option A: In case of low bone density, once the head has reached the bone, it is necessary to swing the upper tip, in order to twist the screw off

• Option B: In case of high bone density, the screw will twist off prior to final positioning. It is therefore required to complete the screwing with the hand screwdriver (REF XTV002001)

After final insertion, it is recommended to confirm the final position under fluoroscopy. When the osteotomy is stabilized, reshape the metatarsal head with a saw.

Note:
Do not use Twist-Off screws in osteoporotic bones
Twist-Off Screws

2.7mm KS screws

The following example describes a Chevron osteotomy with a 2.7mm KS screw.

Joint Preparation/Osteotomy

The Chevron osteotomy is performed through a standard lateral approach to the first MTP joint. Remove the medial eminence and proceed to the Chevron ("V") cut:

- Insert the K-Wire in the center of the metatarsal head depending on the required osteotomy
- Perform a V-shaped osteotomy at the head-neck level at an angle of 60°, with the apex at the K-Wire

The head will follow the direction which is predetermined by the K-Wire placement.

- Translate the capital segment laterally

Screw Placement

After screw length estimation, insert the twist-off screw, without pre-drilling, with a power tool following the same methodology described on Page 18 for the WS Screw.

After final insertion, it is recommended to confirm the final position under fluoroscopy.

Note:

Do not use Twist-Off screws in osteoporotic bones
### Ordering Information – Implants

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* Add an “S” to the REF for Implants Delivered Sterile

** Custom order, Delivered Sterile only
## Ordering Information – Implants

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**Cannulated compression screw**

* Add an “S” to the REF for Implants Delivered Sterile

### Twist-Off Screw

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<thead>
<tr>
<th>REF</th>
<th>Screw Length mm</th>
<th>Distal Thread Ømm</th>
<th>Distal Pitch mm</th>
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<td>WS12</td>
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</tr>
<tr>
<td>WS13</td>
<td>13</td>
<td>2.0</td>
<td>0.85</td>
</tr>
<tr>
<td>WS14</td>
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<tr>
<td>WS15</td>
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<td>WS16</td>
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**Twist-Off Screw**

<table>
<thead>
<tr>
<th>REF</th>
<th>Screw Length mm</th>
<th>Distal Thread Ømm</th>
<th>Distal Pitch mm</th>
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<tbody>
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<td>1.0</td>
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<td>KS16</td>
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<td>1.0</td>
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## Ordering Information – Instruments**

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<thead>
<tr>
<th>REF</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>2.5mm SV Instrumentation</strong></td>
<td></td>
</tr>
<tr>
<td>XTV004001</td>
<td>Cannulated screwdriver Hex 1.8mm</td>
</tr>
<tr>
<td>XTV006001</td>
<td>Screwdriver bit Hex Ø1.8mm AO quick coupling</td>
</tr>
<tr>
<td>XFO051201</td>
<td>Cannulated drill bit &amp; countersink Ø1.7mm L12mm, AO*</td>
</tr>
<tr>
<td>XFO073200</td>
<td>Cannulated drill bit Ø1.7mm L32mm, AO*</td>
</tr>
<tr>
<td>XFO030170</td>
<td>Ruler Ø1.0mm/L70-100mm</td>
</tr>
<tr>
<td>XDB001001</td>
<td>Cleaning pin</td>
</tr>
<tr>
<td>XPI001001</td>
<td>Scarf forceps</td>
</tr>
<tr>
<td>AGK09070M</td>
<td>K-Wire Ø0.9mm L70mm Marked, Tips trocar*</td>
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<tr>
<td>AGK0209070M</td>
<td>K-Wire Ø0.9mm L70mm Marked, Tips trocar/smooth*</td>
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<tr>
<td><strong>3.0mm HV Instrumentation</strong></td>
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</tr>
<tr>
<td>XTV001001</td>
<td>Cannulated screwdriver Hex 2mm</td>
</tr>
<tr>
<td>XTV006002</td>
<td>Screwdriver bit Hex 2mm AO quick coupling</td>
</tr>
<tr>
<td>XFO021201</td>
<td>Solid drill bit &amp; countersink Ø2.0mm L12mm, AO*</td>
</tr>
<tr>
<td>XFO021701</td>
<td>Solid drill bit &amp; countersink Ø2.0mm L17mm, AO*</td>
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<tr>
<td>XFO022301</td>
<td>Solid drill bit &amp; countersink Ø2.0mm L23mm, AO*</td>
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<td>XFO023101</td>
<td>Solid drill bit &amp; countersink Ø2.0mm L31mm, AO*</td>
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<td>Cannulated drill bit &amp; countersink Ø2.0mm L23mm, AO*</td>
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<tr>
<td>XJA002004</td>
<td>Gauge L0 – 40mm</td>
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<td>XJA030170</td>
<td>Ruler Ø1.0mm/L70 – 100mm</td>
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<tr>
<td>AGK10070</td>
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<td>K-Wire Ø1.0mm L70mm, Tips trocar/smooth*</td>
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* Single Use - Custom order per countries
** According to the Complete tray options
# Ordering Information – Instruments**

<table>
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<td><strong>3.5mm CS Instrumentation</strong></td>
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<tr>
<td>XTV001001</td>
<td>Cannulated screwdriver Hex 2mm</td>
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<td>Screwdriver bit Hex 2mm AO quick coupling</td>
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<tr>
<td>XFO021201</td>
<td>Solid drill bit &amp; countersink Ø2.0mm, L12mm, AO*</td>
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<td>XFO021701</td>
<td>Solid drill bit &amp; countersink Ø2.0mm, L17mm, AO*</td>
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<td>XFO043101</td>
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<td>Gauge L0 – 40mm</td>
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<td>XME001001</td>
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* Single Use - Custom order per countries
** According to the Complete tray options
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* Custom order
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* Custom order