

Subject: eIFU – electronic Instructions for Use

Dear Customer,

Stryker Trauma and Extremities (T&E) would like to introduce you to eIFU (electronic Instructions for Use). Since 2017, Stryker T&E has provided Instructions for Use (IFUs) both in paper format in the product packaging (if applicable), and in electronic format on the eIFU website. As our customer, you have access to the paper IFU that is delivered with the product, as well as the electronic version on the website. The content of both versions is identical, only the style is different (e.g. paper size, font size, colors etc.). Additionally, the eIFUs are provided as standalone files for each language as opposed to the multilingual paper IFU.

Now, Stryker T&E is beginning the process of removing the paper IFU from the product packaging and will provide the IFU only in electronic format on the dedicated eIFU website: <https://ifu.stryker.com/>.

There will be many benefits after eIFUs are fully implemented:

- Environmental aspects –reduction of paper waste, and possible smaller packaging sizes.
- Easier revision control of Instructions for use: the latest version will always be readily available.
- One single source where you can view and download IFUs for the whole Stryker T&E product portfolio. In addition to the eIFU, you will also be able to search for additional labeling documents associated with a product, such as:
 - The eGlossary describing the meaning of the symbols used on our labels, on the IFU, but also on the products themselves,
 - The dedicated Operative Technique describing the steps to perform the surgery
 - The Instructions for Cleaning, Sterilization, Inspection and Maintenance
 - The Assembly/Disassembly instructions.

Please note that the removal of the paper IFU from the packaging of T&E products will happen gradually, therefore it is possible that you will receive products both with and without the paper IFU, depending on the manufactured batches.

The following symbol indicates whether the IFU is available in electronic format:



Figure 1: eIFU identifier

Further information will be provided on the product packaging about how to access the eIFU website, and how to order a free paper copy, which is sent to you within 7 days.

This information can be found either on a separate supplemental sticker or enclosed on the inner pages of a peel off label:



Figure 2: Supplemental sticker



Figure 3: Peel off label

Peel off the highlighted corner in order to open the label. On the inner pages of the label, you will find additional information regarding eIFU.

The Stryker eIFU website is accessible with the following hardware and software requirements.

- **Hardware requirements**
 - Availability of Computer/Tablet/Mobile phone
 - Internet connection
 - **Software requirements**
 - The website can be opened with any web browser (such as MS Internet Explorer, Mozilla Firefox, Google Chrome).
 - To view the IFUs, which are available as PDF (Portable Document Format) you need to have a PDF viewer installed on your computer/Tablet/Mobile Phone.
- A free version of the Adobe PDF viewer can be downloaded here: <https://www.adobe.com/>.

Please find below a detailed description of how to navigate the Stryker eIFU website and retrieve the correct IFU (Similar directions can also be found on the homepage of the Stryker eIFU website):

1. Type www.ifu.stryker.com in the address bar of your browser, and press on the search button (Figure 4).
2. You will automatically be directed to the home page of the Stryker eIFU website in your preferred language as the language is set by default in your browser or your operating system. Otherwise, choose your preferred language on the right top corner, by clicking on the drop down menu and selecting the language (Figure 5).
3. On the search field of the Direct download tab (Figure 6), enter the article number (REF) or the GTIN number (the digits below the barcode, between the two numbers in brackets, see highlighted example in Figure 7).

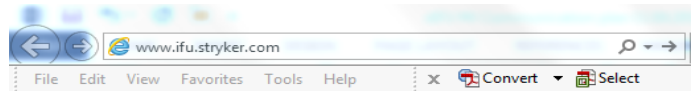


Figure 4: Address bar



Figure 5: Language selection



Figure 6: Search field of the Direct download tab



Figure 7: Main label – REF and GTIN

4. Hit “enter” on your keyboard or click on the search button to show the results (**Figure 8**).
5. On the results page, all associated labeling documents for the entered product are listed in all available languages (**Figure 8**).
6. Click on the document and language of your choice.

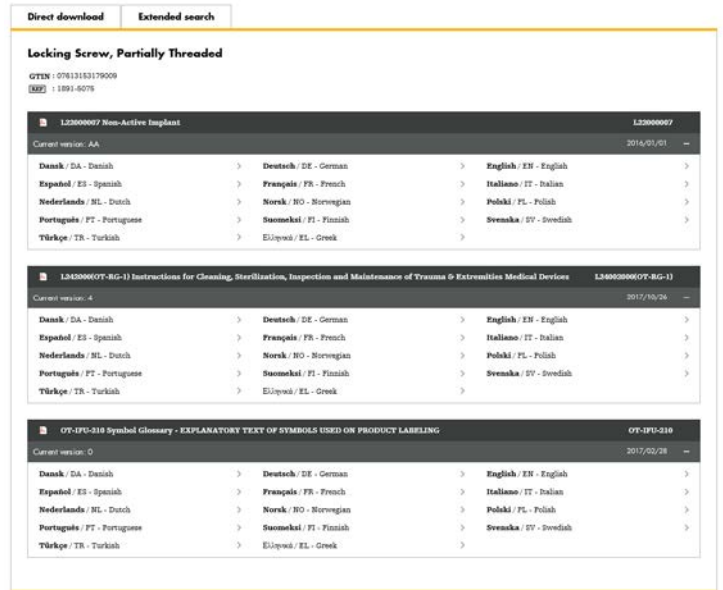


Figure 8: Result page

7. Enter the security code shown in the picture at the top of the page (**Figure 9**).
8. Click on “download PDF”.



Figure 9: Security code entry and PDF download

9. Accept the pop-up message to confirm version control (**Figure 10**).
10. The document will open on your computer or digital device.



Figure 10: Confirm Version

An advanced search option by keywords is also available through the “Extended search” tab. To use it, follow the steps below.

1. In the search field of the Extended search tab, enter any key word describing the product you are searching for, and select a Division (**Figure 11**)
2. Hit enter on your keyboard or click on the search button to show the results.

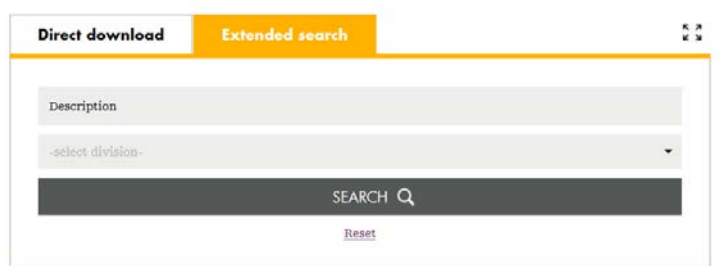


Figure 11: Search field of the Extended search

3. On the results page, you will find a list of all related products matching your search (Figure 12).
4. Click on the desired item, and you will be redirected to the dedicated product page showing all the associated labeling documents (see Figure 8 above).
5. Click on the document and language of your choice.
6. Enter the security code shown in the picture at the top of the page (see Figure 9 above).
7. Accept the pop-up message to confirm version control (see Figure 10 above).
8. The document will open on your computer or digital device.

UDAGVIN number: 00000000000000000000	RefCatalog number: 1800-0010	Description: X-Ray Blade, Femur
Serial number:	Division: Trauma & Extremities	>
UDAGVIN number: 00000000000000000000	RefCatalog number: 1800-0100	Description: Ball Holding Screw, Femur
Serial number:	Division: Trauma & Extremities	>
UDAGVIN number: 00000000000000000000	RefCatalog number: 1800-1000	Description: Target Device, Femur
Serial number:	Division: Trauma & Extremities	>
UDAGVIN number: 00000000000000000000	RefCatalog number: 1800-0011	Description: X-Ray Blade, Femur, A/B
Serial number:	Division: Trauma & Extremities	>
UDAGVIN number: 00000000000000000000	RefCatalog number: 07700000	Description: Distal Locking Femur Plate
Serial number:	Division: Trauma & Extremities	>
UDAGVIN number: 00000000000000000000	RefCatalog number: 07700000	Description: Distal Locking Femur Plate
Serial number:	Division: Trauma & Extremities	>
UDAGVIN number: 00000000000000000000	RefCatalog number: 07700000	Description: Distal Locking Femur Plate
Serial number:	Division: Trauma & Extremities	>

Figure 12: Result page for extended search

You can also order a paper copy of your eIFU, at no additional cost, by following the steps below

To order a free paper copy, you need a telephone.

1. Consult the eIFU information on the product package (Figure 2 and 3).
2. Locate the call center phone number of your geographical area (indicated by the two digits country codes). The call center is available 24 hours a day, 7 days a week.
3. Call the number and follow the operator instructions.
4. Provide the address where you would like to receive the paper copy of your eIFU.
5. The paper copy of the eIFU will be delivered at the indicated address without any additional cost, and within 7 days.

FAQs

<p>1. How do I enter the article number (REF)?</p>	<p>As it is shown on the label, including any special characters (dash, slash, period, etc.), for example:</p> <p>181755 1891-5075 1847-0003S 99-0028/11F WA/B-NL 500.220</p>
<p>2. Why there are no results shown?</p>	<p>Not all Stryker T&E products have an IFU. If there is no IFU associated with a certain product, the following message will be displayed: "document not found". Please contact info@e-labeling.eu, or your sales representative.</p>
<p>3. Who do I contact if I need assistance for the download?</p>	<p>24 hours a day, 7 days a week.</p>
<p>4. When is the call center available to order a free paper copy of the eIFU?</p>	<p>24 hours a day, 7 days a week.</p>

Sincerely yours,

Karoline Poppe
Labeling and Technical Publication
Stryker Trauma and Extremities