

EN

STAR™ Sterile Single-Use Instruments

INSTRUCTIONS FOR USE

V15156 Rev AA, 01-2017 (LBL 2210)



Manufacturer:

Stryker GmbH
Bohnackerweg 1
2545 Selzach, Switzerland
Phone: +41 (0) 32 641 66 66
Fax: +41 (0) 32 641 66 60

CONTENTS

INSTRUCTIONS FOR USE

1	Product insert	3
2	Contents	3
3	Description & material	3
4	Intended use & indications for use	3
5	Precautions	4
6	Storage	4
7	How supplied	4
8	Inspection, function & maintenance	4
9	For further information	4
10	Explanation of symbols and abbreviations used on product labels	5

STAR™ Sterile Single-Use Instruments

INSTRUCTIONS FOR USE



ALL OF THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE

1 Product insert

Important Medical Information for using the Sterile Single-Use Instruments

2 Contents

The package contains one or more Sterile Single-Use Instruments.

3 Description & material

The Sterile Single-Use Instruments consist of various surgical burs, reamers, mills, sawblades, stabilizing pins, and drill bits used to cut, drill, and/or shape small and long bones in preparation for implantation of a medical device.

The instruments are made from surgical grade 316LS stainless steel (ASTM F138), 304 stainless steel (ASTM A276), 455 stainless steel, 465 stainless steel, or PH15-7Mo stainless steel (ASTM A564).

The instruments in their packaging have been sterilized by gamma radiation which has been validated to assure a Sterility Assurance Level of 10^{-6} .

4 Intended use & indications for use

Ensure that you are familiar with the recommended uses, compatibility and correct handling of the instrument; please remember that product systems may be subject to alterations that affect the compatibility of the instrument with other instruments or with implants! Please refer to the compatible implant instructions for use.

WARNING

- The instruments are intended for single use only. Single use is defined as use of one implant or instrument on a single patient in a single surgical procedure. Reuse of instruments designated as single use has been associated with necrosis of bone leading to implant failure. It may also lead to sepsis and/or communication of potentially lethal viruses.
- The most common cause of instrument breakage is misuse. Specialty instrumentation should never be used for tasks it was not specifically designed to perform. Misuse of an instrument may result not only in damage to the instrument, but also trauma to the patient or operating room personnel.

- If not handled properly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgical gloves.
- If an instrument tip becomes bent, chipped, or otherwise damaged the instrument shall be replaced. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromised in the process, and the instrument may subsequently break during use.

5 Precautions

- The instrument is provided sterile in an undamaged package. If either the instrument or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the instrument shall not be used. **Do not re-sterilize.**
- The surgical techniques for implantation of the associated implantable medical devices describe the proper application of specialty instrumentation and should be read and understood by the surgeon prior to use.

6 Storage

- The sterile instruments are packed in protective packaging that is labeled according to its contents.
- Store the sterile instruments in the original protective packaging. Do not remove the sterile instrument from the packaging until it is ready to be used in surgery.
- Store the packaged instrument in normal hospital environmental conditions.

7 How supplied

Sterile Single-Use Instruments are single use and shall not be re-sterilized or reprocessed.














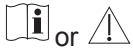


8 Inspection, function & maintenance

Visually inspect for damage, wear and corrosion. Cutting edges shall be free of nicks and present a continuous edge. Discard blunt, damaged, or corroded instruments.

9 For further information

Please contact Stryker or your authorized representative if further information on this product is needed.

10 Explanation of symbols and abbreviations used on product labels

	Catalogue number
	Batch code
	Date of manufacture
	Manufacturer
	Use by date
	Sterilized using irradiation
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
QTY	Quantity
	Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician
	Non-sterile
	Sterilized using ethylene oxide
	Keep dry
	Consult instructions for use
	Fragile, handle with care
	Keep away from sunlight