








Galea Set sterile (comprising 4 hooks and 4 cords)	
REF: EEF-9	
Accessories: - Clamp, z.B. PEAN	
	Disposable product, do not reuse!
	Only trained medical personnel may use or dispose of the galea hooks!
<p>This instruction is not a substitute for reading the instructions for use of products used in parallel with the galea hooks.</p> <p>The Galea Hook packaging unit contains four hooks and four silicone cords each.</p> <p>Galea hooks are intended for short-term use (> 60 min. to 30 days).</p>	
Intended use	
The Galea Hooks are used for self-retaining elastic distention or spreading of tissue. Specifically, they have been designed for retraction of the galea during interventions in/on the skull.	
Indications and contraindications	
Indications - Exposure of structures beneath the skin tissue	
Contraindications - None known	
Possible adverse effects	
When using Galea Hooks, the retracted tissue may be unavoidably traumatized.	
Prior to use:	
	<p>Check sterility and packaging for integrity! Using products from damaged packaging is associated with the risk of infection! Do not use products from damaged packaging and return them to the manufacturer! Do not use products whose expiration date has passed! Risk of infection!</p>
	<p>Perform a safety check prior to use. Check the integrity of the geometry, especially for cracks or fractures! Use only products of sound quality! Handle hooks with care! Avoid striking the instrument or applying pressure to its parts! Risk of damage → Risk of injury!</p>
	<p>When pulling the silicone cord through, pay attention to the tips of the hooks to avoid damaging the gloves or injuring the skin. Risk of injury! Use only sterile products of sound quality!</p>



For preparation purposes, simply pull approx. half of the silicone cord through the eyelet of the hook.

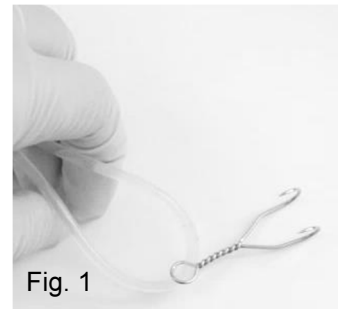


Fig. 1

During use:



During use, do not place more pressure on the tissue being retracted than absolutely necessary for the surgical purpose.

The scalp is dissected from the skull bone. Place the hook in the appropriate place of the incision and anchor it in the skin tissue. (Simulated in the illustrations by foam material).

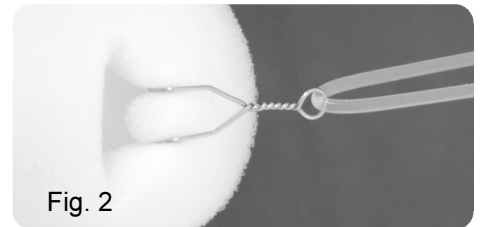


Fig. 2

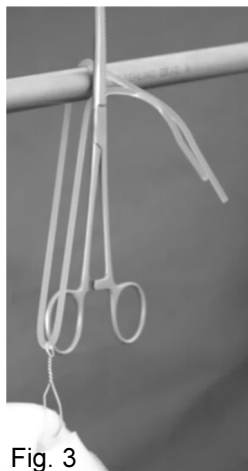


Fig. 3

Attach the silicone cord to a suitable retractor system or retaining element as may be available in the department, for example, the THOREXPO EEJ-2 angulated rod (Fig. 3) in conjunction with the adapting clamp EEK-1F. The adjustable FEHLING system (Fig. 4), consisting of the adapting clamps EEJ-4 and the retaining bars EEJ-5 (left) and EEJ-6 (right) is the ideal holding system. (Full instructions are described in IFU G111.) The Cords are secured with a Pean clamp (Figs. 3 and 4).

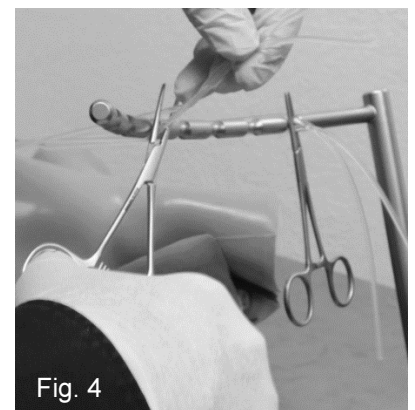


Fig. 4



Overstretching and excessive compression of the silicone cord with the clamp can cause tearing and thus injury to patient and user.

After use



Dispose of Galea Hooks and Cords in accordance with regulations in the collection container available for disposable products used in the operating theater.

Do not reprocess, do not reuse!

Single-use product – risk of infection if reused!















Transport and storage conditions



Silicones such as the SIC 8363 used here are elastic and heat-resistant between -20°C and 55°C. The shelf life of the silicone product is 2 years from production.

Observe the expiration date! Do not use after the expiration date!



Explanation of symbols:					
					
Instrument for single use - do not reuse!	Follow the In- structions for Use!	Warning!	Use by	Article number	Batch code
					
Sterilized with ethylene oxide	Do not use if packaging is dam- aged!	Store in a dry place!	Protect from excessive heat!	Manufactu- rer	Notified Body
	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.				
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