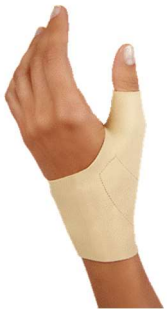
FICHE TECHNIQUE
Flexible thumb brace EPITACT

Juin 2021
050-Indice C



Distribution area	Commercial denomination	Size	Reference
	Usual pack: 135 x 12 x 157 mm, 5,31 x 0,47 x 6,18 in.		
AL	Flexible Aktivitäts-Daumenbandage Rhizarthrose	**L**	0593DAL
			0593GAL
		M	0592DAL
			0592GAL
		S	0591DAL
			0591GAL
BE	Orthèse Pouce souple d'activité Rhizarthrose / Soepele Duimorthese Rhizarthrose	**L**	0593DBE
			0593GBE
		M	0592DBE
			0592GBE
		S	0591DBE
			0591GBE
EN	Flexible Thumb Brace	**L**	0593DEN
			0593GEN
		M	0592DEN
			0592GEN
		S	0591DEN
			0591GEN
ES-CINFA	Muñequera arthrosis de pulgar - Farmalastic	**M**	CIN592D
			CIN592G
		P	CIN591D
			CIN591G
			CIN593D
			CIN593G
FR	Orthèse Pouce souple d'activité Rhizarthrose	**L**	0593D
			0593G
		M	0592D
			0592G
		S	0591D
			0591G
IT	Ortesi Pollice Flessibile Dinamica Rizoartrosi	**L**	0593DIT
			0593GIT
		M	0592DIT
			0592GIT
		S	0591DIT
			0591GIT
PT	Órtese Polegar Flexível diurna	**L**	0593DPT
			0593GPT
		M	0592DPT
			0592GPT

		S	0591DPT
			0591GPT
SU	Flexible Aktivitäts-Daumenbandage Rhizarthrose / Orthèse Pouce souple d'activité Rhizarthrose / Ortesi Pollice Flessibile Attività Rizoartrosi	**L**	0593DSU
			0593GSU
		M	0592DSU
			0592GSU
		S	0591DSU
			0591GSU
ES	Ortesis Pulgar flexible de actividad	**L**	0591DES
			0593DES
			0593GES
		M	0592DES
			0592GES
		S	0591GES
Distributeur	Orthèse Pouce souple d'activité Rhizarthrose	**L**	0593DD
			0593GD
		M	0592DD
			0592GD
		S	0591DD
			0591GD
	Retail pack: 85 x 157 x 20 mm, 3,35 x 6,18 x 0.78 in.		
DK	EPITACT - SMIDIG TOMMELFINGERSKINNE - HØJRE	L	593DDK
		M	592DDK
		S	591DDK
	EPITACT - SMIDIG TOMMELFINGERSKINNE - VENSTRE	L	593GDK
		M	592GDK
		S	591GDK
NL	Flexibele Duimbrace Pijnlijke duim	**L**	593DNL
			593GNL
		M	592DNL
			592GNL
		S	591DNL
			591GNL
UK	Flexible Thumb Brace Painful Thumb	S	591DUK
			591GUK
		L	593DUK
			593GUK
		M	592DUK
			592GUK

Description	The device is made up of a specific pattern matching the curve of the hand by: - Silicone gel, EpitheliumFlex, - And in polyamide elastane fabric
Technical data	• To free itself from the use of reinforcements which prevent the gripping function of the hand, the EPITACT® Research & Development team sought to design an orthosis whose patronage, by virtue of its specific shape, naturally positions the thumb. in a resting position,

	aligning it with the first metacarpal. This orthosis was the subject of a patent EP3041441 (B1). • Its effectiveness on traumatic micro-movements has been confirmed by a study carried out under extreme conditions of use: the karateka gesture. It highlights the function of maintaining the thumb with the EPITACT® orthosis during a sudden movement: the thumb is higher, the amplitudes of movement are smaller, the micromovements disappear and the return to a stop is faster . • • In October 2014, a questionnaire was sent to mail order customers to see if users noticed any relief. 174 validated ballots were received. 157 revealed pain relief of 90%.
Indications	Rhizarthrosis or osteoarthritis joint pain
Contra-indications	Contraindications: do not use on damaged skin
Advantages	The EPITACT flexible thumb orthosis allows full functionality of the hand during the day. It is complementary to rigid orthoses, suitable for night wear.
Composition	• 86 % fabric polyamide/elasthanne, • 14 % silicone
Maintenance	Machine washable at 30 ° C in the washing net provided. No chlorine - No ironing, no steam - No machine drying - No dry cleaning.
Sizes	 S: 13 ≤ ◯ ≤ 15 cm M: 15 < ◯ ≤ 17 cm L: 17 < ◯ ≤ 19 cm Measure the circumference of the wrist. Exist for the right or left hand.
Packaging	Cardboard case, with dimensions: - Usual pack: 135 x 12 x 157 mm, 5,31 x 0,47 x 6,18 in. - Retail pack: 85 x 157 x 20 mm, 3,35 x 6,18 x 0.78 in. Sold by unit
Storage conditions	No specific storage conditions
Cautions of use	This device is an orthosis for daily use only.
Ec marking	The products described in this document comply with the GENERAL SAFETY AND PERFORMANCE REQUIREMENTS of European Union Medical Device Regulation 2017/745 of June 2017. They bear the CE mark, which is marked by the CE logo. In accordance with Appendix VIII European Union Medical Device Regulation 2017/745, the products described in this documentation belong to Class I.
Biocompatibility	Biocompatibility of the materials was evaluated according to ISO 10 993-1 for medical device coming into contact with the skin.