Product Portfolio 2009

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Fall Prevention

KPH Hip Protector

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The KPH Hip Protector is a medical aid to prevent femoral Hip Fractures. The KPH consists of an undergarment with pockets on both sides that contain a semi-rigid shield. The shields are removable and have a universal size that fit all panties. The KPH Hip Protector is CE certified as a Medical Device Class 1.

- Hard on the outside soft on the inside.
- Removable protectors, long lifespan.
- Available in 7 different sizes, Male and Female.
- Suitable for machine washing (60°C) and drying.
- Thoroughly tested
- Easy to use
- Discreet

How it Works

The shields of the KPH Hip Protector are designed to absorb the shock of an impact to the hip caused by a fall and to diffuse the force to the surrounding muscles and soft tissue. With the unique two-part design of the KPH, the impacting force and energy are first weakened by the padding part of the protector and then diverted away from the greater trochanter by the shield part. (Age Ageing 2006).

The newest hip protectors that emphasize a thin and soft design seem to seek increased user comfort, but this is most likely achieved at the cost of reduced force attenuation, efficacy, and SAFETY (Lancet 2003).

Care

Before washing the KPH Hip Protector undergarment the protection shields need to be removed from the side pockets.

- The undergarment can be machine washed in warm water (40°C) and tumbled dried at medium heat.
- The protection shields should be hand washed only, using a suitable washing detergent.

Fitting Instructions

The KPH Hip Protector is easy to use!

Step 1: Insert one shield into each of the pockets in the undergarment, as illustrated on the outer surface of the shield, and zip the pockets closed.

Step 2: Slip on the undergarment as any undergarment. The shields will be automatically placed in the right position, above the trochanter.

The KPH Hip Protector is specially made for ease of use and increased comfort whilst wearing hip protectors. The KPH Hip Protector can be easily worn all day and all night.

"50% of women who reach the age of 90 have suffered a hip fracture"

American Academy of Orthopedic Surgeons

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Size

The size of the KPH panty needs to be chosen carefully, in order to position the shields on the hips. Accurately measure the waist and use the table below to select the correct garment size.

Waist measurement

Size Chart	Waist Size Women (cm)	Waist Size Men (cm)
XS	58-65	70-77
S	66-74	78-85
M	75-81	86-93
L	82-89	94-101
XL	90-101	102-109
XXL	102-114	110-117
XXXL	115-127	118-125

The protectors are available in one size and fit all panties

Really Clinically Proven!

Not surprisingly, after the first randomized controlled trials with hard shield type hip protectors were published there was a rapid increase in a wide variety of hip pads and protectors on the market….But not all hip protectors have been created equal….(Lancet 2003). For example, a study by O'Halleron and colleagues (Age Ageing 2004), that tested the SafeHip© hip protector, among 4117 nursing home residents, showed a larger number of hip fractures in the intervention group than in the control group.

In view of these findings, it is unfortunate that most commercially available hip protectors have reached the market with a spectacular dearth of scientific research. …Many types of hip devices are available with unsubstantiated claims for fracture prevention. References to scientific publications in peer-reviewed journals are absent, or, when investigations are mentioned, the studies do not relate to the device in question (Lancet 2003).

Despite the increasing recognition among physicians and patients that hip protectors could be an essential preventive measure for hip fracture, few models of protectors have been studied systematically (Lancet 2003).

The newest hip protectors that emphasize a thin design seem to seek increased user comfort, but it is most likely achieved at the cost of reduced force attenuation, efficacy and SAFETY (Lancet 2003).

It would be prudent to anticipate the scenario of an older person who is wearing a hip protector falling and suffering a hip fracture, as no device can provide complete protection. Such a catastrophic event may lead to legal action against the manufacturer, supplier or caregiver. This means that those recommending specific hip protectors must be armed with scientific evidence that the protector has been proven to effectively reduce the force to the proximal femur in a sideways fall, and, according to a large randomized trial, reduce fractures among users (Lancet 2003).

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Hip protectors that are brought to the market should ensure documentation of the biomechanical anti-fracture efficacy of the selected protector *in vitro* and in actual falls, continuing with compliance and adherence amongst users, and ending with a user-control comparison in a randomized trial (Age and Ageing, 2006 & Lancet 2003)

The KPH Hip Protector is the only hip protector that successfully went through all the above mentioned steps and of which all data is published in peer reviewed journals (N Engl J Med 2000, J Bone Miner Res 1995, Calcif Tissue Int 1997, Bone 1999 & 2006, Age Ageing 1998).

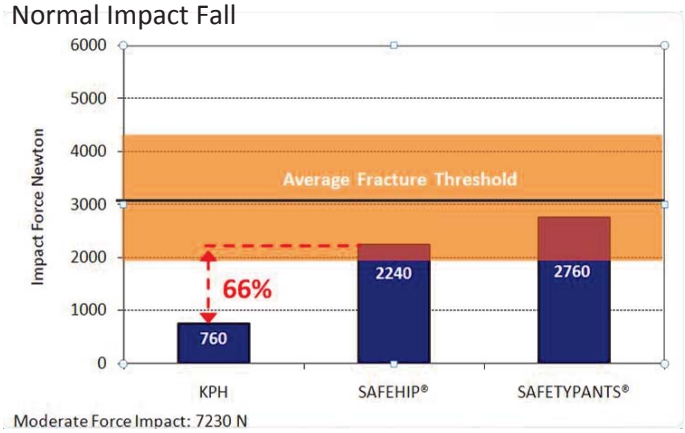
KPH: Biomechanical Superiority!

A sound hip protector research and development program should start with biomechanical impact studies.

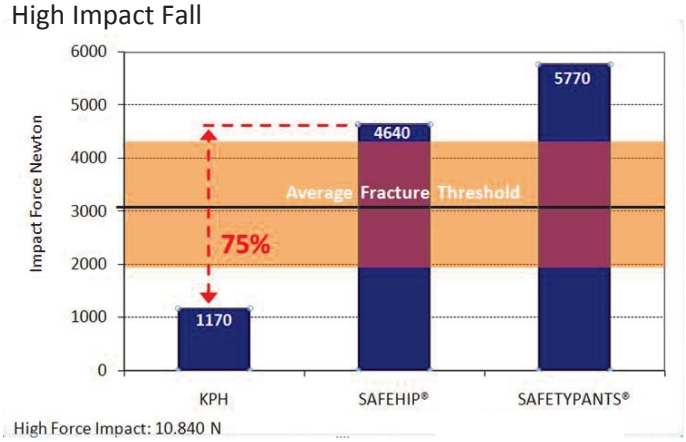
Three studies, of which two are published in peer reviewed scientific journals prove that the KPH Hip Protector offers the highest impact reduction of all hip protectors tested (Bone 1999 & 2006, Tampere University 2000).

Kannus et al (Bone 1999) compared the impact force reduction of the KPH hip protector with the Safehip© and Safetypants©. They simulated a low, moderate and high impact fall. During all three tests the KPH showed the largest impact reduction. Only the KPH was capable of reducing the impact force of the simulated moderate and high impact fall below the average fracture threshold (± 1 SD).

Normal Impact Fall



High Impact Fall



The authors concluded: “Of the hip protectors tested, only the KPH Protectors can provide effective impact force attenuation in a sideways-fall simulation in the elderly. The force attenuation capacity of SafeHip® and SafetyPants® seems more limited.”

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User Compliance

The second step in hip protector research is to assess the user compliance. A study published in Age and Ageing (1998) concluded: On average 90% of the residents wore the KPH Hip Protector in their daily activities.

True Clinical Evidence

The last and most important step before launching a hip protector on the market should be a large user-control comparison in a randomized trial.

The KPH is tested in a large (*n* = 1801) randomized multicentre trial and showed, with intention-to-treat analysis, that the risk of hip fracture was 60% less in the protector group than in the control group and that by protector efficacy or active treatment analysis, the risk reduction was >80% if the protectors were actually worn at the time of falling (N. Engl. J. Med. 2000)

According to the intention-to-treat analysis, the number needed to treat (NNT) to avoid one hip fracture was 41 persons for one year, or eight persons for 5 year (N Engl. J. Med. 2000). The KPH Hip Protector is the only hip protector with a number needed to treat.

The clinical effectiveness of the KPH is proven in a large clinical trial that is published in the prestigious New England Journal of Medicine (2000)

The wider results of randomized studies with mechanically weaker hip protectors have, however, been less encouraging (Age Ageing 2003, Osteoporoses Int. 2004, Age Ageing 2001, Inj. Prev. 2003, BMJ 2003, JAMA 2003, Age Ageing 2004).

Next to the KPH Hip Protector the only Hip Protector that was studied in large clinical trials is the SafeHip©. To date the SafeHip© is clinically tested on more than 6500 individuals. Unfortunate the total number of participants in the trials that proved hardly or no effect is more than 4800. (Age Ageing 2001, JAMA 2003, Lancet 1993, Osteoporoses Int. 2001, BMJ 2003, Age Ageing 2004).

The SafeHip© studies show disappointing results. Small studies such as Harada et al (n=164) show a large fracture reduction. However, due to the low number of participants this reduction is not statistically significant. Larger studies such as O'Halloran (Age Ageing 2004) with 4117 participants, and Van Schoor (2003) with 561 participants show hardly or no difference at all in fracture reduction between the control and intervention group.

These results with the SafeHip© protector were to be expected, taken in to consideration the results of a study published in Bone (1999) which featured a biomechanical study. In this biomechanical study the SafeHip© Hip Protector was not able to reduce the impact force during medium and hard falls properly.
When the two largest clinical trials performed with the KPH and SafeHip© are compared the difference is clear.

	KPH	SafeHip©
Participants	1801	4117
Scientific Journal	N. Engl. J. Med.	Age Ageing
Publication Date	2000	2004
Authors	Kannus	O'Halleron
Cluster Randomized Trial	Yes	Yes
Setting	Institutional	Institutional
HIP FRACTURE REDUCTION	60%	0%

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Hip Fractures

Hip Fractures are a major threat to the health and well-being of elderly people, because these fractures represent one of the most important causes of longstanding pain, functional impairment, disability, and death in this population. These are over 1.5 Million Hip Fractures annually worldwide (Lancet 2003).

Who requires a KPH Hip Protector?

If you are concerned by at least two of the following risk factors, then it is recommended to wear a KPH Hip Protector.

Source: Cummings et al 1995, Hindson 1998, Meilainen et al 2002.

Facts

- More than 1.5 million Hip Fractures per year worldwide
- Nearly 1.000 Hip Fractures a day in the US
- More than 1/3 of people over the age of 65 fall each year

Consequences

A Hip Fracture has severe consequences

Financial consequences:

- $11,5 billion: cost for acute and convalescent care of hip fracture in the US (2001)
- $33.000 per patient

Personal consequences:

- Decreased physical functioning, disability, loss of independence and reduces quality of life

- Requires (home) care (50%)
- Full recovery (25%)
- Die within 12 months (25%)

Caregiver burden:

- Greater rates of hospitalization, physician contacts, and help for routine daily activities (e.g. bathing, dressing, food preparation...)

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