

Saving time, trauma and energy

DIANATAL[®]
obstetric gel



The new option

Dr. Andreas F. Schaub

2009 / Zurich
Specialist OB/GYN FMH
Founder, Chairman & CEO
HCB Happy Child Birth Inc.

Evolution: Birthing as selection

“Having in mind all the special characteristics of human reproduction as high birth weight, big head/brain, short interbirth intervals, high perinatal mortality rate and low adult mortality rate, it can be illustrated that in summary the evolutionary role of the birthing process in humans can be seen as a positive selection pressure of nature: to induce a high perinatal mortality by the traumatic birthing process leading overall to an optimization of the genetic profile, the physical health state and the energy conservation needs in mothers and newborns.” AFS 2003

The unmet needs in obstetrics

safety increase

&

pain / birth experience improvement



Maternal unmet needs: - pain/birth experience
- pelvic floor damage (fecal & urinary incontinence)
- vaginal damage (postpartum sexual dysfunction)

Fetal unmet needs: - asphyxia / CP
- birth trauma / RDS
- vertical infection (GBS, HIV)

Child Birth is labor !



Work to overcome friction

That is why multiparous women deliver faster, with less pain and with much lower complications than primiparous

Friction is no fiction !

Moolgaoker et al. Obstet Gynecol 1979 Sep; 54(3):299-309

- “The amount of compression acting on the fetal head would be modified by several factors, including the experience of the operator, **the coefficient of friction of the maternal tissues**, the size of the baby, and also the choice of the instrument.”
- “Lindgren showed that the **expulsive force of uterine contractions is equivalent to 33 pounds.**”
- “Numerous reports suggest that a **traction force of 50 pounds might be considered the upper limit of safety**, and yet many normal babies have been delivered by pulls in excess of 50 pounds.”

Theoretic impact of Dianatal

Primary benefits:

labor facilitation, pain reduction,
reduction of delivery time

work/time



- delivery time
- use of analgetics

Secondary benefits:

reduction of maternal and fetal
morbidity/mortality

trauma



- forceps/vacuum extraction rate
- pelvic floor damages/lacerations
- newborn trauma

costs



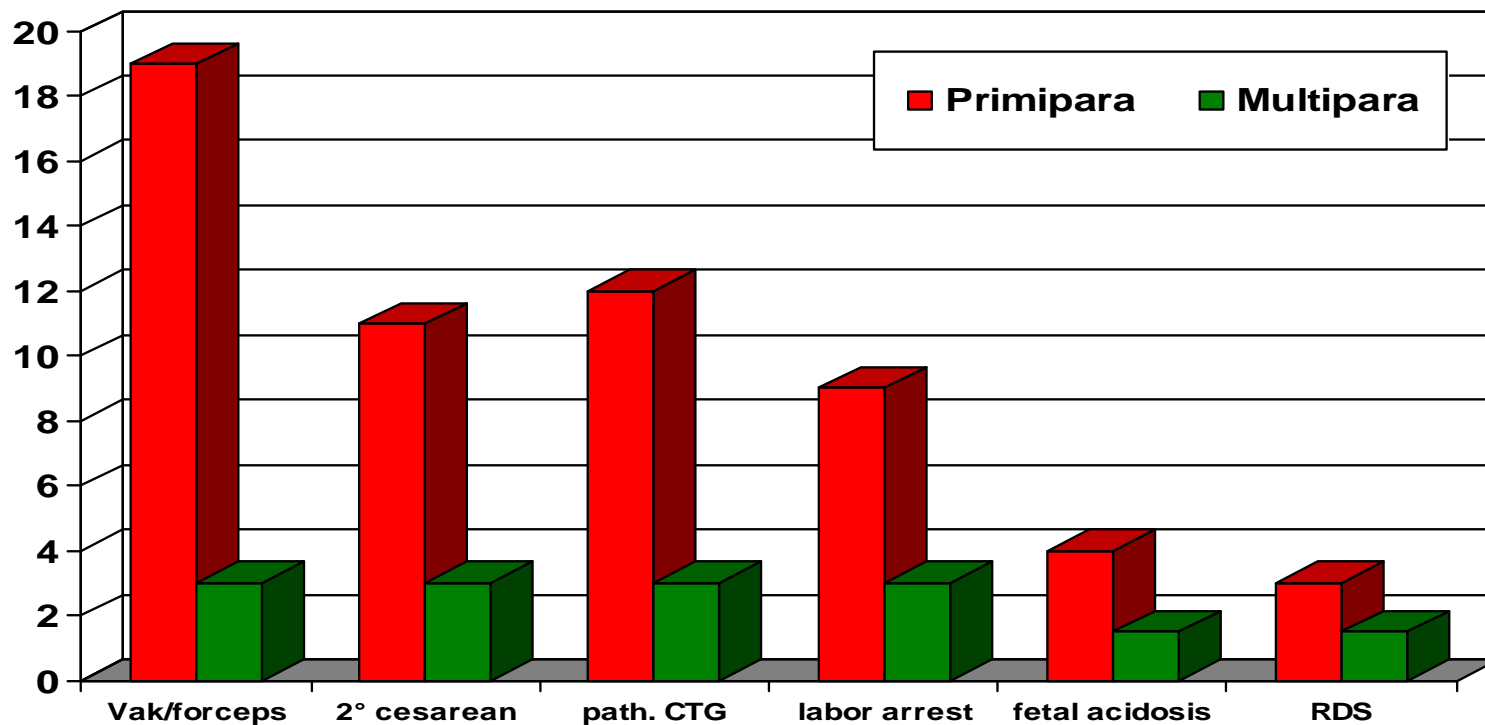
- maternal and fetal outcomes

The HCB Parity Adjusted Outcome Study 2004

- period: 1993 until 2003
- Switzerland
- Source: 352'215 deliveries, ASF nationwide statistics
- Discriminating factor: friction [parity & birth weight (4000 g)]
- Included very low risk deliveries: 188'339
 - Primipara: 82'003
 - Multipara: 103'106 (2 to 4)
 - Grandpara: 3230 (> 4)

Labor outcomes depend on friction


all = P < 0.001



labor outcomes are significantly dependent on friction

Every women's dream

DIANATAL[®]
obstetric gel



- a quick and easy delivery
- with maximum security for herself and the child
- an experience one can not describe

A step towards the dream



Dianatal® Obstetric Gel

New in Human Obstetrics –

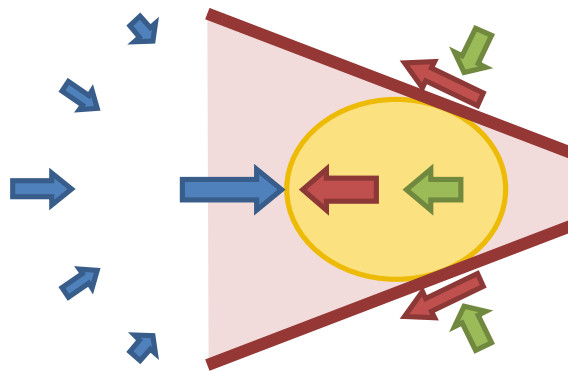


Although a Gold Standard in Vetmed

- ~ 80: Soranus of Ephesus: Olive Oil
- 1972: Japan Patent: Alginic Acid
- 1986: US Patent: Plastic Foils
- 2002: European Patent: Dianatal

Significantly reduces the opposing friction force and facilitates vaginal childbirth saving time and energy.

ETH Zurich: Friction is no fiction



Newborn expulsion

= uterine contractions

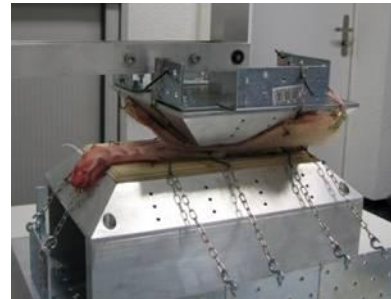
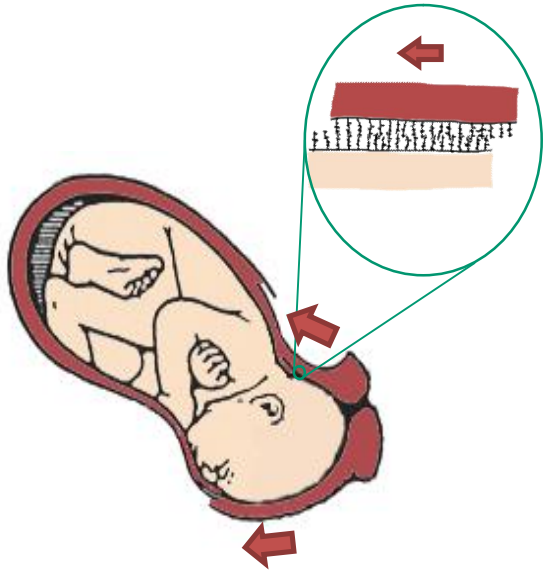
minus elastic forces

minus friction force

(friction coefficient/newborn mass)

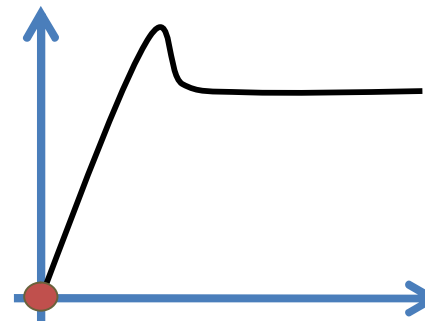
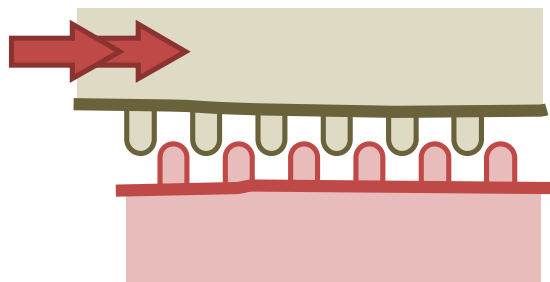
Dianatal[®] Obstetric Gel

ETH Zurich: Birth model



ETH Zürich: Birth model

adhesion friction / gliding friction



ETHZ: birth model results



1. Dianatal reduces adhesive friction significantly by 50 %
2. Dianatal reduces gliding friction significantly by 50 %
3. **Not every Gel is a Birth Gel:**
Dianatal Stage 1 and Stage 2 show different effects: Dianatal Stage 1 influences adhesive friction more effectively

Control: water

Preventative use: results

HCB Swiss Study 2005 to 2007:

- randomized prospective trial with active control at three Swiss Obstetrics Dept.
- active control, blinding not possible, placebo not possible

347 primiparous women randomized into

- Group A: standard of care without Dianatal Obstetric Gel
- Group B: standard of care with Dianatal Obstetric Gel

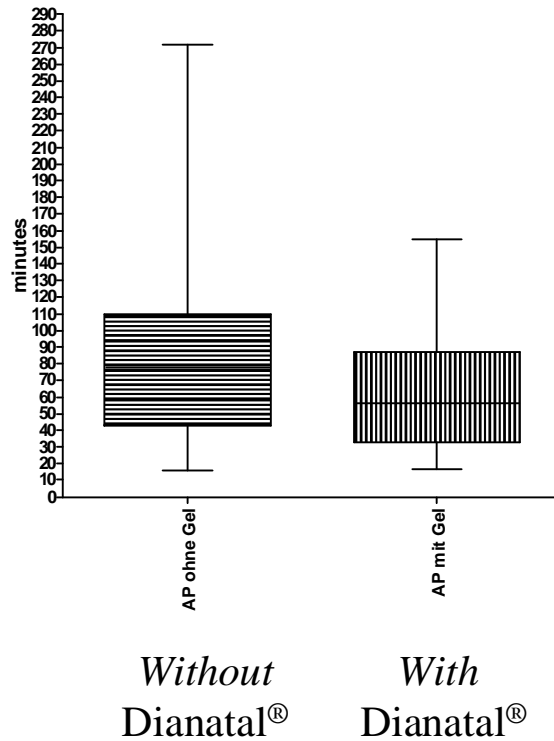
- Intervention: Dianatal application onto the birth canal starting at early labor stage 1 (before 4 cm dilatation) End points: Labor duration, perineal outcomes, intervention rates

- Study report/surveillance: Prof. Dr. J. Drewe, Dept. for Clinical Pharmacology, University Hospital Basel:

- Centers: Cantonal Hospital Frauenfeld, Cantonal Hospital Schaffhausen,
University Hospital Basel

Results of Frauenfeld und Schaffhausen:

Published: J. Perinat. Med. 36 (2008) 129-135



Dianatal®:
Reduces labor stage 2 significant
by 26 min

N = 74, delta 26 min, $p < 0.05$ ($p = 0.026$)

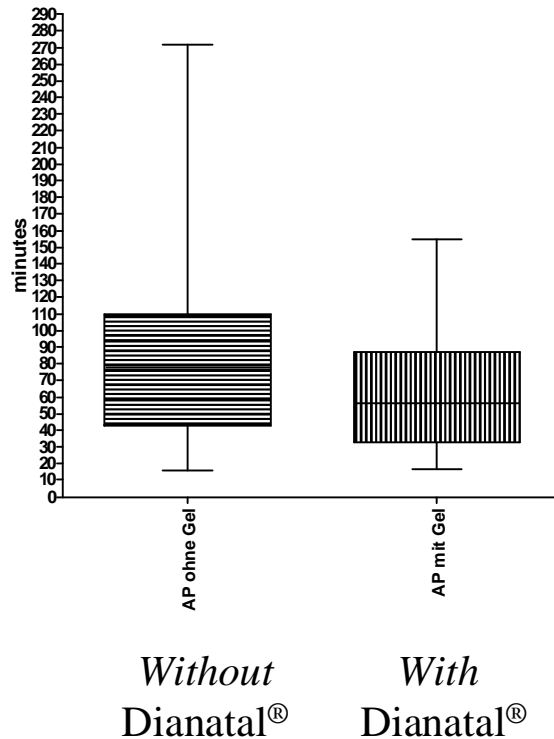
Stage 2 without Dianatal: 88 min
Stage 2 with Dianatal: 62 min

Delta: 29 %

group +/- EDA +/- AMN

Results of the three study centers:

Presentation PD Dr. I. Hösli, Hamburg 2008



Dianatal[®]:
Reduces labor stage 2 significant
by 22 min

N = 106, delta 22 min, p < 0.05 (p = 0.016)

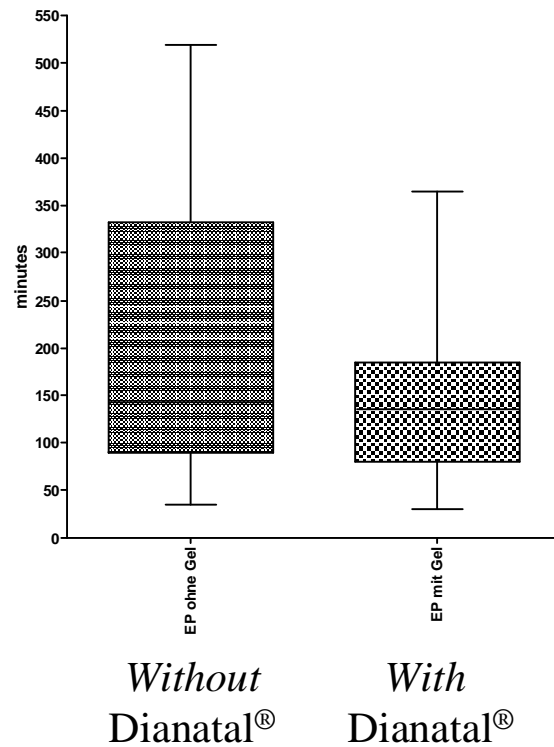
Stage 2 without Dianatal: 81 min
Stage 2 with Dianatal: 59 min

Delta: 27 %

group +/- EDA +/- AMN

No center effect, but application quality matters: Dianatal effect was highest in FF (FF > SH > BS)

Results of Frauenfeld und Schaffhausen:
Published: Human Study Report, Januar 2007, Prof. J. Drewe



Dianatal®:
Reduces labor stage 1 significant
by 65 min

N = 47, delta 65 min, p < 0.05 (p= 0.049)

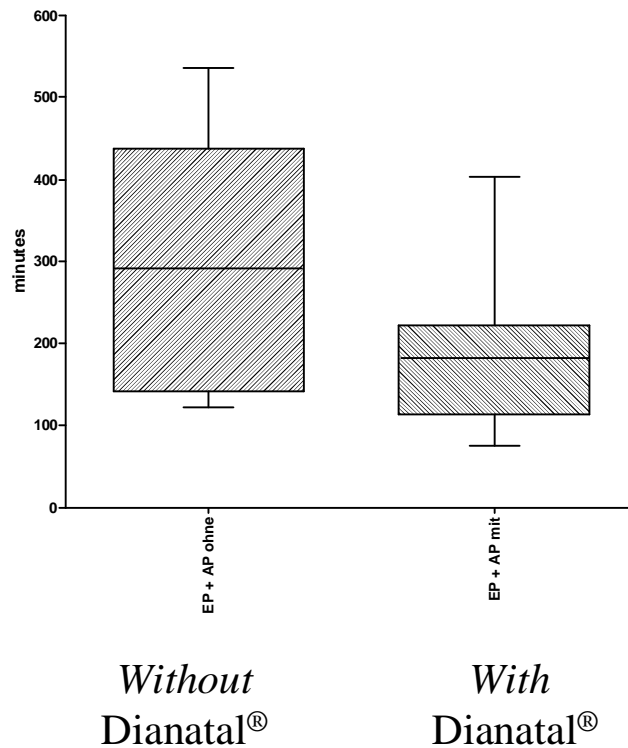
Stage 1 without Dianatal: 203 min
Stage 1 with Dianatal: 138 min

Delta: 32 %

Group without EDA +/- AMN

Results of Frauenfeld und Schaffhausen:

Published: Human Study Report, Januar 2007, Prof. J. Drewe



Dianatal®:
Reduces Stage 1&2 significant
by 106 minutes

N = 31, delta 106 min, p < 0.05 (p = 0.015)

Stage1&2 without Dianatal: 294 min
Stage1&2 with Dianatal: 188 min

Delta: 36.15 %

group without EDA without AMN

Preventative use: results summary of the different groups

Labor Duration Outcomes in Patients with Land Births in an occipito-anterior position

Summary table of all groups:

	N	Labor stage	Mean reduction in min	Median reduction in min	Mean reduction in %	Median reduction in %	P value
Q +/- PDA +/- Amn	74	2	26.35	22.00	29.90	28.21	0.026
Q +/- PDA + Amn	21	2	14.64	28.00	20.40	36.84	n.s.
Q +/- PDA - Amn	53	2	32.72	19.00	34.08	24.36	0.035
Q + PDA +/- Amn	27	2	30.39	19.00	29.00	20.21	n.s.
Q - PDA +/- Amn	47	2	21.05	20.00	27.42	28.57	0.086
Q + PDA + Amn	5	2	not calculated				
Q + PDA - Amn	22	2	41.55	28.00	36.30	29.79	n.s.
Q - PDA + Amn	16	2	15.63	26.50	22.82	37.86	n.s.
Q - PDA - Amn	31	2	24.45	14.00	30.00	20.00	n.s.
Q +/- PDA +/- Amn	74	1 & 2	48.92	82.00	16.47	28.87	n.s.
Q +/- PDA + Amn	21	1 & 2	54.22	66.50	18.09	22.66	n.s.
Q +/- PDA - Amn	53	1 & 2	46.80	83.00	15.82	29.23	n.s.
Q + PDA +/- Amn	27	1 & 2	-39.04	-8.50	-12.11	-2.96	n.s.
Q - PDA +/- Amn	47	1 & 2	86.00	71.50	30.75	28.21	0.014
Q + PDA + Amn	5	1 & 2	not calculated				
Q + PDA - Amn	22	1 & 2	-45.73	-1.00	-15.36	-0.35	n.s.
Q - PDA + Amn	16	1 & 2	48.12	15.50	18.94	7.26	n.s.
Q - PDA - Amn	31	1 & 2	106.41	109.50	36.15	37.56	0.015
Q +/- PDA +/- Amn	74	1	22.57	25.00	10.80	15.15	n.s.
Q +/- PDA + Amn	21	1	39.58	47.50	17.37	20.88	n.s.
Q +/- PDA - Amn	53	1	14.09	12.50	7.05	8.33	n.s.
Q + PDA +/- Amn	27	1	-69.42	-65.00	-31.89	-36.11	n.s.
Q - PDA +/- Amn	47	1	64.95	7.50	32.00	5.26	0.049
Q + PDA + Amn	5	1	not calculated				
Q + PDA - Amn	22	1	-87.27	-90.00	-47.64	-60.00	n.s.
Q - PDA + Amn	16	1	32.50	-30.00	17.51	-22.22	n.s.
Q - PDA - Amn	31	1	81.97	35.00	38.51	21.21	0.056

Q = oa position, land births without intervention; analysis of variance: PDA:= peridural ; Amn:= Amniotomy

Results of Frauenfeld und Schaffhausen:

Published: J. Perinat. Med. 36 (2008) 129-135



Significant reduction of perineal tears: risk twofold reduced.

N = 95, odds ratio 2.7, p < 0.05

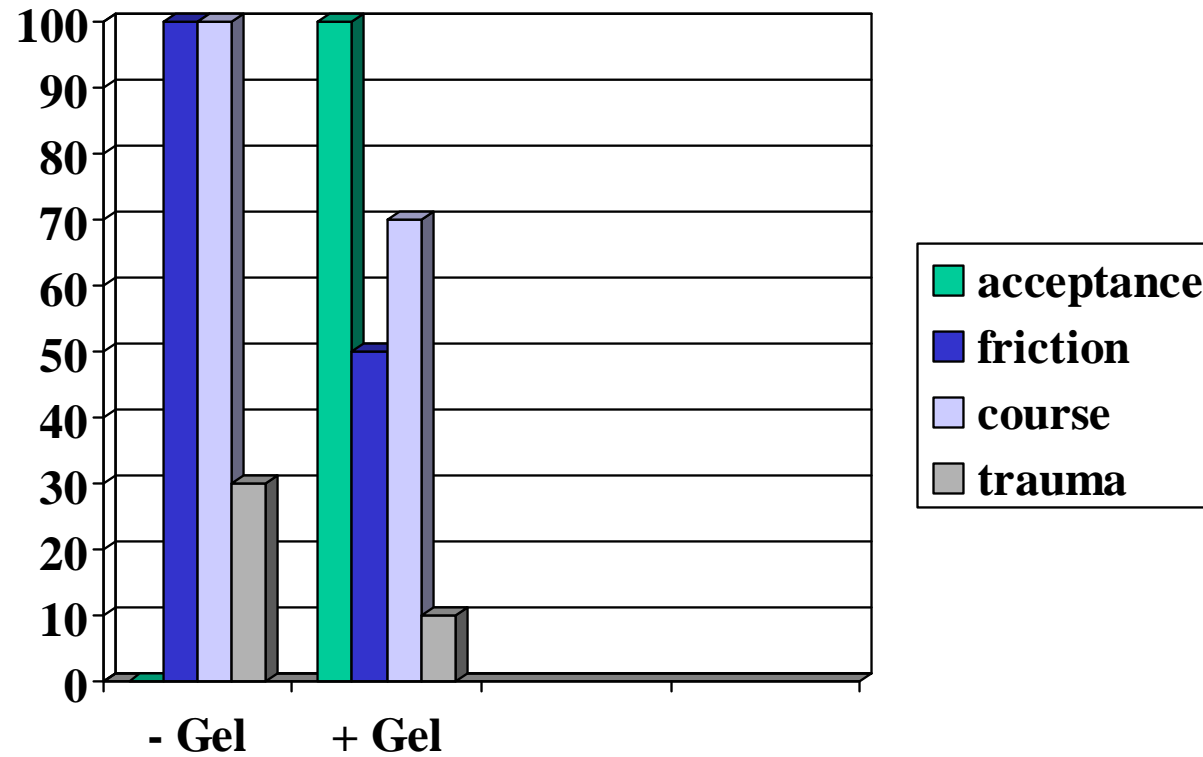
	N	Intact perineum diff.	Odds Ratio	p value
Spontaneous	74	14%	2.2	0.072
Kristeller	21	22%	8	0.068
Spontaneous and Kristeller	95	15%	2.7	0.024

Therapeutic use: results

University Marburg, Prof. Dr. M. Kühnert:

- investigational observation in the therapeutic use of Dianatal (n =65)
- Indications:
 - Labor arrest
 - Obstructed or delayed delivery
- Preterm delivery
- Dry vagina after use of prostaglandin for labor induction
- Facilitation of vaginal operative procedures
- Facilitation of manual placenta delivery
- Indication for labor facilitation in case of history with C-section, state after obstructed labor, big baby, borderline pelvic size

Therapeutic use: results



Therapeutic use: results



Marburger Impressions on Dianatal in therapeutic use:

- The defined goals are achieved
- Dianatal reduces friction and „treats“ labor arrest
- Dianatal reduces labor stage 2 significantly
- Dianatal reduces perineal tears

Dianatal® Obstetric Gel



- Reduces labor duration significant by 30 % in primiparous women
 - Stage 1: up to 65 min, Stage 2: up to 33 min
- Protects pelvic floor, vagina and perineum (twofold risk reduction for laceration)
- Is safe and shows no side effects, facilitates vaginal operative procedures and shows efficacy in obstructed labor

Scientific outlook



The reduction of vaginal-operative delivery rates and C-section rates by the use of Dianatal could be further investigated by a randomized prospective Multicenter Study.

The reduction of vertical infection transmission by the use of Dianatal could be investigated by a randomized prospective Multicenter Study. (Group B Streptococcus, HIV)

Dianatal® obstetric gel kit

DIANATAL®
obstetric gel



- **3 sterile single-use 11ml syringes**
 - **2 Stage 1**
highly bioadhesive
 - **1 Stage 2 (blue piston)**
moderately bioadhesive
- **2 sterile single-use Dianatal applicators**
- **instructions for use**



- **CE marked: Medical Device Class II a: CE 0197**
- **Patent protected: EP 1467707**
- **Swiss invention**
- **Manufactured in Germany**

Not every Gel is a Birth Gel !

DIANATAL®
obstetric gel



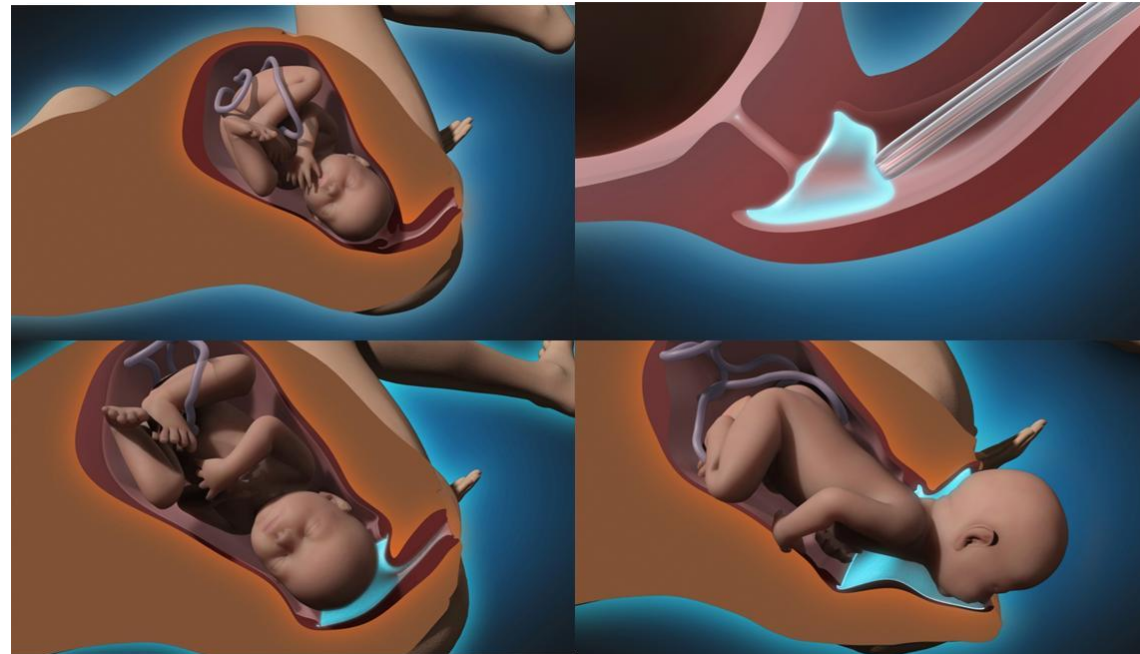
- **Dianatal® birth gel is**

- **Sterile**
- **Non-allergenic, non pyrogenic**
- **Bioadhesive**
- **Bacterizide** (B Strept, A-Strept., Gardn., E.coli)
- **Electroconductive, isotonic**
- **Latex-free**
- **Free of preservatives**
- **Kind on mucous tissue and eyes**

- **and fully biocompatible**

Agar diffusion test, Buehler sensitization test, Embryotoxicity test, Human blood hemolysis test, Intracutaneous injection test, Oral irritation test, Primary ocular irritation test, Primary skin irritation test, Primary vaginal exposure test, Rabbit pyrogen test, Systemic injection test

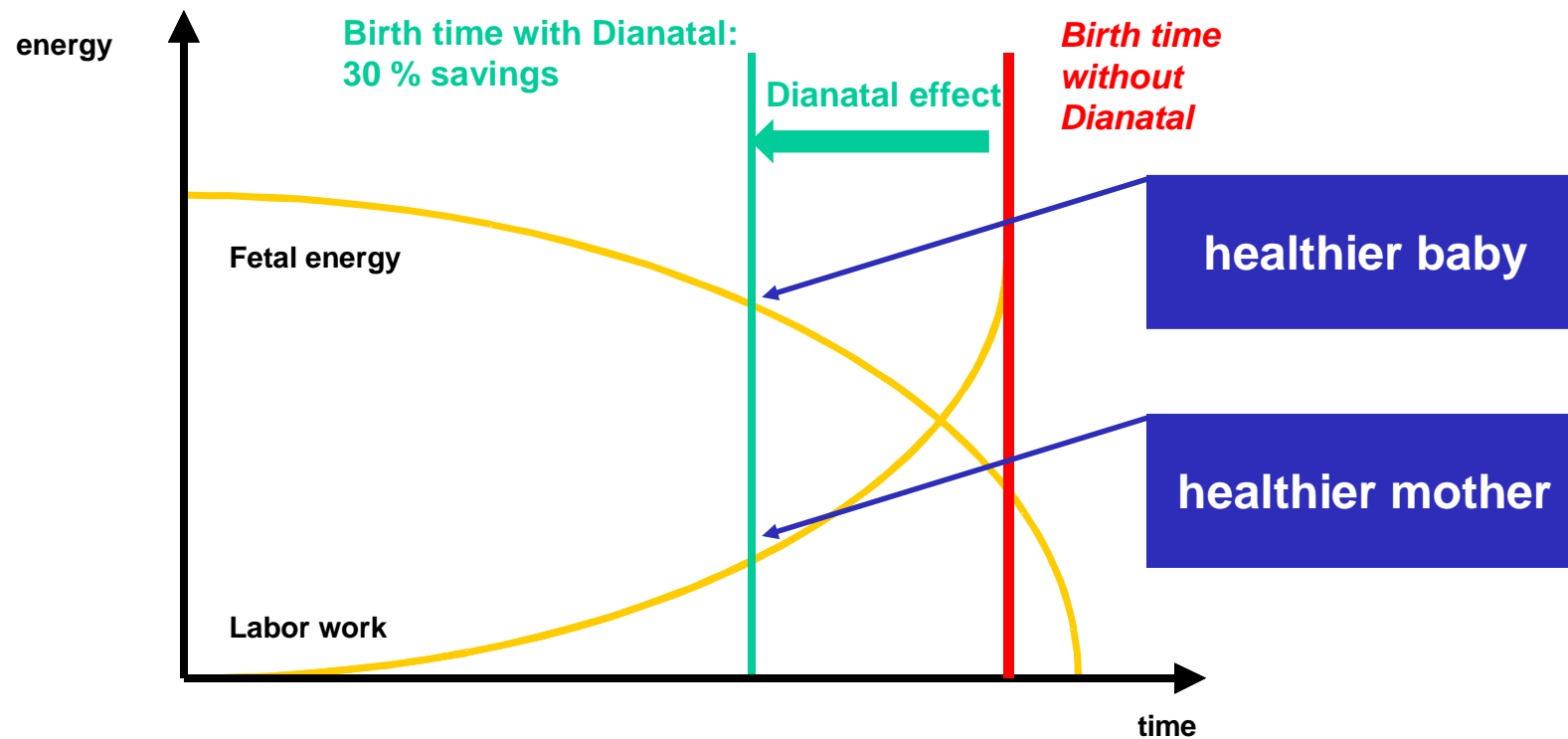
Gel Birth: instructions for use



- 3 to 5 ml Dianatal® is administered in a two hours interval to the presenting part after vaginal examinations
- Dianatal® Stage 1 is preferably used during the Stage 1
- Dianatal® Stage 2 is preferably used during the Stage 2
- Do use 20 to 30 ml of Dianatal® obstetric gel in total to ensure optimal child birth facilitation. Ad fluid in dry vaginal conditions
- Do use a dry towel during delivery to prevent slipping

Delivery time shift - a **big** difference

Shift towards left means **time and energy savings**



26 / 106 minutes
a step towards the dream

DIANATAL[®]
obstetric gel



Thank you